

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B5622A - JV	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/EP2005/003988	International filing date (day/month/year) 30.03.2005	Priority date (day/month/year) 31.03.2004	
International Patent Classification (IPC) or national classification and IPC INV. A61K47/10 A61K47/12 A61K47/26 A61K47/36 A61K47/38 A61K47/40 A61K9/19 A61K9/20			
Applicant CHIESI SA			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  27.01.2006		Date of completion of this report  16.06.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer  Giménez Miralles, J  Telephone No. +49 89 2399-	



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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-30 as originally filed

**Claims, Numbers**

1-41 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 1,20,21,28,31,22,35,40 in part  
because:
    - ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
    - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
    - ☒ the claims, or said claims Nos. 1,20,21,28,31,22,35,40 in part are so inadequately supported by the description that no meaningful opinion could be formed.
    - ☒ no international search report has been established for the said claims Nos. 1,20,21,28,31,22,35,40 in part
    - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
      - the written form ☐ has not been furnished
      - ☐ does not comply with the standard
      - the computer readable form ☐ has not been furnished
      - ☐ does not comply with the standard
    - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
  - ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-41
Inventive step (IS)	Yes: Claims	
	No: Claims	1-41
Industrial applicability (IA)	Yes: Claims	1-41
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Re Item III**

An incomplete international search has been carried out for the parts of the present claims 1-41 as construed by taking in combination independent claims 1, 20, 21, 28, 31, 22, 35 and 40 with dependent claims 2, 3 and 4, in accordance with the description and the examples, because the International Searching Authority considers that the independent claims do not comply with the requirements of Articles 5 and 6 PCT (claims broader than justified by the disclosure of the invention), thereby rendering a meaningful complete search impossible (see International Search Report, Box II.2).

The applicant's attention is drawn to the fact that claims relating to subject-matter in respect of which no international search report has been established need not be the subject of a written opinion (Rule 43*bis*.1(b) and Rule 66.1(e) PCT).

In this regard, the present written opinion is restricted to the subject-matter mentioned above.

**Re Item V**

1. The relevant prior art documents are referred to as D1 to D8 as in the order of appearance in the International Search Report (ISR). Unless otherwise indicated, reference is made to the passages of said documents cited in the ISR.
2. Citations and explanations supporting the statement with regard to novelty (N), inventive step (IS) and industrial applicability (IA) (Rule 43*bis*.1(a)(i) and (b) PCT):

- (N) The subject-matter of claims 1-41 (see Item III above) is not novel because it is anticipated by the prior art (Article 33(2) PCT).

Documents D1 to D4 anticipate solid particulate compositions (granulates, agglomerates) obtained by freeze-drying a mixture comprising an unpalatable active ingredient, an organic acid (e.g. citric acid or fumaric acid), a binder (such as a polysaccharide, xanthan, gelatin, etc.), and a filler (such as dextrose, or saccharose, etc.). Therefore, nothing new can be seen in the subject-matter of the present independent claims.

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(IS) The subject-matter of claims 1-41 is not considered to involve an inventive step (Article 33(3) PCT) for the reasons mentioned above.

In case that the invention is directed to compositions comprising piroxicam/beta-cyclodextrin, then D5 would be relevant for the assessment of inventive step.

In case that the invention is directed to specific binders and fillers, then D1-D4, D6 and D7 would be relevant for the assessment of inventive step.

(IA) The subject-matter of claims 1-41 is considered to be industrially applicable (Article 33(4) PCT). The possibility of industrial application is beyond any doubt.